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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/826,004	BRAIG ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *28-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Claims 28-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/13/06.

Applicant's election with traverse of Group I in the reply filed on 12/13/06 is acknowledged. The traversal is on the ground(s) that a proper search for art related to the elected Group would necessarily include the classes and subclasses relevant to a search for the non-elected Group and thus would not present a serious burden on the examiner. This is not found persuasive because the search for a group is not limited to a class and/or subclasses. Since the particulars of the method, as claimed, are not identical to the particulars of the system, as claimed, the search strategy for each differs. Therefore, the search and examination of the entire application would present serious burden.

The requirement is still deemed proper and is therefore made FINAL.

The election requirement between species A and B has been reconsidered and is hereby withdrawn. In view of the withdrawal of the election requirement and the claims withdrawn due to the election of Group I, claims 1-27 are examined in this Office action.

Claim Objections

Claim 21 is objected to because of the following informalities:

Claim 21 recites, "further comprising a terminal", which is a further structural limitation. However, claim 21 is drawn to a method. The language "further comprising providing a terminal" should replace the recited language.

Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 27 recites providing an insulin delivery pen, the pen comprising "a microcontroller configured to make available a measured dosage of insulin for injection into a patient". The instant specification lacks sufficient antecedent basis for such a microcontroller in the insulin delivery pen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> Or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14 and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,024,699 to Surwit et al. Surwit teaches a method of managing a diabetic condition wherein a meter 12 is configured to calculate a correction bolus using a correction algorithm and to measure a concentration in a material sample from a patient, the analyte being an indicator of a diabetic condition (see entire document, especially col. 7, lines 42-64; col. 8, lines 18-63 of Surwit). The result of the measurement is a variable used in the correction algorithm (see entire document, especially fig. 11 of Surwit). A server 14 is provided in two-way communication with the meter 12 and is configured to store information received from the meter (see entire document, especially fig. 1; col. 6, lines 31-36; col. 8, lines 18-55; col. 9, lines 25-51 of Surwit). A medical caregiver is allowed to access the server using a terminal 16 in two-way communication with the server 14 and is allowed to modify the correction algorithm via the terminal 16 (see entire document, especially fig. 1; col. 6, lines 36-39; col. 8, lines 47-55; col. 10, lines 1-4 and lines 25-34; col. 18, lines 47-58; col. 19, lines 40-65 of Surwit).

Regarding claim 2, the variables used by the correction algorithm to calculate the correction bolus comprise patient-affected variables (see entire document, especially fig. 11 of Surwit) and caregiver-affected variables (see entire document, especially col. 18, lines 48-54 of Surwit).

Regarding claim 3, modifying the correction algorithm comprises at least changing a value of a caregiver-affected variable, changing a time interval between

prompts for the meter for measurements, or requesting an additional measurement (see entire document, especially col. 18, lines 48-58 of Surwit).

Regarding claim 4, modifying the correction algorithm comprises changing a value of a caregiver-affected variable, said caregiver-affected variable being a target analyte concentration (see entire document, especially col. 18, lines 50-54 of Surwit)

Regarding claim 5, the caregiver is allowed to request additional action form the patient via the meter (see entire document, especially col. 18, line 48-col. 19, line 7 of Surwit).

Regarding claim 6, the requesting additional action comprises requesting a measurement of a ketone body (see entire document, especially col. 18, lines 55-58 of Surwit), wherein, since the caregiver can control the level of glucose at which a test for urine ketones is requested via the meter, the caregiver is thereby requesting additional action from the patient via the meter.

Regarding claim 7, the patient-affected variables comprise at least measured glucose concentration (see entire document, especially fig. 11 of Surwit).

Regarding claim 8, the caregiver-affected variables comprise at least a time interval between measurements (patient's self-monitoring schedule; see entire document, especially col. 18, lines 54-55 of Surwit).

Regarding claim 9, the meter is a handheld meter (see entire document, especially table 1 of Surwit).

Regarding claim 10, Surwit teaches a method for communicating patient information to a caregiver for use in managing a diabetic condition of a patient wherein

a meter 20 is provided and associated with the patient. The meter is configured to measure a concentration of an analyte and to at least temporarily store the results of the measuring (see entire document, especially col. 7, line 15-col. 8, line 35 of Surwit). The meter is configured to communicate with the caregiver by presenting the caregiver a choice of at least one diabetes-relevant datum for communication by said meter to caregiver (see entire document, especially col. 9, lines 50-54; col. 11, lines 15-32 of Surwit).

Regarding claim 11, the at least one diabetes-relevant datum is at lest one of an individual value of a concentration of analyte relevant to said diabetic condition, trends in individual values of analyte concentrations, and a correction bolus consumed by the patient (see entire document, especially fig. 9; col. 7, lines 41-47; col. 9, lines 25-30 and lines 50-54 of Surwit).

Regarding claim 12, he meter is configured to receive a communication of a datum from the caregiver (see entire document, especially col. 8, lines 47-55 of Surwit).

Regarding claim 13, the datum communicated from the caregiver to the meter is at lest a numerical value used by an algorithm to calculate a correction bolus or a request for an additional concentration measurement (see entire document, especially col. 18, lines 47-59 of Surwit).

Regarding claim 14, Surwit describes a method for communicating patient information to a caregiver for use in managing a diabetic condition of a patient wherein a server 14 is provided. The server is configured to communicate with at least a patient specific meter 12 (see entire document especially col. 9, lines 25-51 of Surwit). A

caregiver is presented a choice of at least one diabetic-specific datum for communication from the meter to the caregiver (see entire document, especially fig. 9, col. 7, lines 41-47; col. 9, lines 25-30 and 50-54; col. 11, lines 15-32 of Surwit), wherein, since the caregiver can choose to click on the user's medical condition (col. 18, lines 4-30 of Surwit) a choice is presented. The choice is implemented via the server (see entire document, especially col. 9, lines 50-54; col. 18, lines 4-30 of Surwit).

Regarding claim 17, the server has storage and processing capabilities (see entire document, especially col. 9, lines 50-51 of Surwit). At least one datum relating to the diabetic condition is communicated form the meter to the caregiver (see entire document, especially col. 7, lines 42-58; col. 9, lines 25-29 and lines 50-54 of Surwit). At least one datum relating to the correction bolus is communicated from the caregiver to the meter (see entire document, especially fig. 1; col. 6, lines 36-39; col. 8, lines 47-55; col. 10, lines 1-4 and lines 25-34; col. 18, lines 47-58; col. 19, lines 40-65 of Surwit)

Regarding claims 18 and 19, the terminal for the caregiver comprises a personal digital assistant or desktop computer running a software program configured to communicate with the meter (see entire document, especially col. 10, lines 25-41; col. 11, lines 15-32 of Surwit).

Regarding claim 20, the at least one datum communicated from the caregiver to the meter comprises a variable (parameter) used by the meter to calculate the correction bolus (see entire document, especially col. 18, lines 50-52 of Surwit).

Regarding claim 21, a second terminal is provided for a secondary caregiver and at least one datum relating to the diabetic condition is communicated from the meter to

the secondary caregiver (see entire document, especially fig. 12; col. 19, line 67-col. 20, line 28 of Surwit).

Regarding claim 22, the server is configured to store data related to a diabetic condition (see entire document, especially col. 9, lines 25-29 and lines 50-67; col. 10, lines 1-21 of Surwit).

Claims 10-12 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0069753 to Brown. Brown teaches a method for communicating patient information to a caregiver for use in managing a diabetic condition of a patient, wherein a meter 26, 28 is provided, the meter being configured to measure a concentration of an analyte and to at least temporarily store the results of said measuring (see entire document, especially paragraphs 82, 84, 86, and 90 of Brown). The meter is associated with a patient (see entire document, especially paragraphs 81, 82 of Brown). The meter is configured to communicate with a caregiver by presenting to the caregiver a choice of at least one diabetes-relevant datum for communication by said meter to caregiver (see entire document, especially paragraphs 80, 81, 102, 105, 107 of Brown).

Regarding claim 11, the at leas tone diabetes-relevant datum is at least an individual value of a concentration of an analyte relevant to said diabetic condition or trends in individual values of analyte concentrations (see entire document, especially fig. 10; paragraph 105 of Brown).

Regarding claim 12, the meter is configured to receive a communication of a datum from the caregiver (see entire document, especially paragraphs 107 and 113 of Brown).

Regarding claim 14, the server is configured to communicate with at least one patient-specific meter 26, 28. The caregiver is presented a choice of at least one diabetic-specific datum for communication from the patient-specific meter to said caregiver, and the choice is implemented via the server (see entire document, especially fig. 10; paragraphs 80-82, 84, 86, 90, 102, 105, 107, and 113 of Brown).

Regarding claims 15 and 16, the implementing comprises configuring the meter to send at least one diabetic-specific datum to said server and configure the server to send at least one diabetic-specific datum directly to the caregiver (see entire document, especially fig. 10; paragraphs 105, 107 of Brown).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23- 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit, as applied to claims above, and further in view of US Patent No. 6,482,185 to Hartmann. Surwit teaches the meter calculating a datum relating to a correction bolus to be administered to the patient but is silent as to how the bolus is administered to the

patient. However, Hartmann teaches using a blood glucose meter to determine a correction bolus administered to a patient by an insulin delivery pen (see entire document, especially figs. 8, 9, col. 3, lines 19-37; col. 5, lines 1-18 of Hartmann). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the communication and cooperation scheme between the meter and pen of Hartmann as that in Surwit, as modified, since Surwit, as modified, alludes to administering a correction bolus to a patient, and Hartmann describes an appropriate means for doing so.

Regarding claim 24, the insulin delivery device is an insulin delivery pen (see entire document, especially figs. 8, 9 of Hartmann).

Regarding claim 25, the meter 30c is provided with a port 34, 51 the port being configured to mechanically engage the pen to select an insulin dosage (see entire document, especially figs. 8, 9; col. 3, lines 19-37; col. 5, lines 1-18 of Hartmann). A datum relating to a correction bolus is mechanically communicated to the pen via said port (see entire document, especially col. 5, lines 1-14 of Hartmann)

Regarding claim 26, the port 34, 51 is configured to mechanically engage a dosage selection knob 52 of the pen 10c and to rotate the knob a predetermined amount (see entire document, especially figs. 8, 9; col. 5, lines 1-18 of Hartmann).

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit, as applied to claims above, and further in view of US Patent No. 5,66,065 to Colman et al. Surwit teaches determining a correction bolus, but is silent as to how that bolus is

administered to the patient. However, Colman discloses a medication delivery pen 10' configured to communicate electronically with a glucose meter 16' (see entire document, especially fig. 4; col. 5, lines 15-40 of Colman). The pen comprises a microcontroller configured to make available a measured dosage of insulin for injection into the patient (see entire document, especially col. 5, lines 32-34 of Colman). A datum relating to a correction bolus is communicated electronically from the meter to the insulin delivery pen (see entire document, especially col. 5, lines 29-32 of Colman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the use of the delivery pen and communication scheme between the pen and meter of Colman with the method of Surwit, since Surwit, alludes to administering a correction bolus to a patient, and Colman describes an appropriate method and means for such administration of a bolus to the patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication No. 2004/0167464 to Ireland et al. teaches a blood glucose meter communicating with a delivery device to administer a correction bolus based on a blood glucose meter reading from the meter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571)

272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/pcm

Primary Examiner